RECEIVED AT DRUG SAFETY SURVEILLANCE
27-FEB-1998-0470

McN

McNEIL CONSUMER
FORT WASHING

Page

Individual Safety Report
3037730-2-00

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
19056124	9 mo	( )female	lbs
In confidence	or Date of birth:	(X)male	or 8.3 kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: recovered

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
12/2/94	02/10/98

5. Describe event or problem

Case report requested from [redacted] in preparation for the FDA Nonprescription Drugs Advisory Committee Meeting on Dosing/Labeling of Pediatric Analgesics/Antipyretics held 9/18/97. Report indicates 9 mo old presented to hospital w/HYPOGLYCEMIA, seizures (CONVULSION), & acute hepatic failure (LIVER FAILURE). Three days prior to admission, pt had out-patient surgery for hypospadias repair. Discharge instructions included acetaminophen 120mg q4h. Caretaker mistakenly gave 1.5 teaspoonfuls (90mg/kg/dose) of acetaminophen drops (100 mg/ml). Pt rec'd total of 8 doses over 2 days. Pt presented to ER 1 day prior to admission w/VOMITING & decreased oral intake. Dx w/viral gastroenteritis & sent home. On morning of admission, pt found w/ eyes rolled back, stiff legs & limp upper extremities. ER squad noted glucose= 8 & started D25. In ER, pt experienced tonic-clonic seizures controlled w/diazepam. Pt intubated & transferred to 2nd hosp. On arrival, Pt encephalopathic (ENCEPHALOPATHY) with no focal defects & w/hepatomegaly. (see Sec C10)

6. Relevant tests/laboratory data, including dates

Initial labs: AST=9380, ALT=7126, PT=29.6, and PTT=37.3, serum acetaminophen level=46.8 mcg/ml 24-30 hours after last dose; peak liver func tests: AST=10,520, ALT=7420, PT=24.8, & PTT=32.7

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

former 34 week premie, hypospadias repair 3 days prior to admission

Sect C10 con't: According to report, long term follow-up with pediatrician indicates a healthy 3.5 year old child.

C. Sus

1. Name (give labeled strength & mfr/labeler, if known)

#1 Infants' TYLENOL Drops
#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 90 mg/kg/dose	#1 8 doses over 2 days
#2	#2

4. Diagnosis for use (indication)

#1 post hypospadias repair
#2

5. Event abated after use stopped or dose reduced

#1 (X) Yes ( ) No ( ) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown Sect B5 con't: Tx included FFP, dextrose, vit K, lactulose & NAC via NG tube. Within 24 hrs pt transferred to 3rd hosp. Pt improved & was removed from transplant service & discharged home 4 days afterward. (see Sect B7)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 02/03/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE
CONVULSION
HYPOGLYCEMIA
LIVER FAILURE
VOMITING
ENCEPHALOPATHY

9. Mfr. report number: 0931621A

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	Nurse	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3600A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.